

HC-CE-KZ1-1 Declaration of conformity

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|--------------------------|--|
| Manufacturer:            | Name: Changzhou Huichun Medical Equipment Co., Ltd.<br>Add: Sanhekou, Zhenglu Town, 213115 Changzhou, Jiangsu, People's Republic of China  |
| European Representative: | Name: Shanghai International Holding Corp. GmbH (Europe)<br>Add : Eiffestrasse 80, 20537 Hamburg Germany<br>Tel: +49-40-2513175      Fax: +49-40-255726<br>E-mail: shholding@hotmail.com |
| Product Name             | Disposable Face Mask   |
| Model Number:            | G type and X type  |
| UMDNS-Code:              | 12447  |

Classification (MDD, Annex IX): Class I Rule 1

Conformity Assessment Route: **Annex VII**

We herewith declare that we follow the applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC, according to Rule 1 of Annex IX in MDD93/42/EEC, the face mask is Class I device, it can "CE" marked.

The product concerned has been designed and manufactured under a quality management system according to MDD93/42/EEC Annex VII. Following the procedure relating to the EC Declaration of Conformity set out in MDD93/42/EEC Annex VII This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices. Changzhou Huichun Medical Equipment Co., Ltd. takes full responsibility of the content of Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Signature: \_\_\_\_\_

Name: Mr. Xiaobo Zheng

Place & Date: Changzhou, Jiangsu, China 2020-03-26

Position: General Manager

